IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM CORPORATION and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, Plaintiffs, v. APOTEX INC. and APOTEX CORP., Defendants.	**PUBLIC VERSION** C.A. No. 23-685 (CFC) [redacted] Confidential Version Filed: April 4, 2025 Public Version Filed: April 9, 2025

STIPULATION REGARDING STAY OF LITIGATION

WHEREAS, Plaintiffs Boehringer Ingelheim Pharmaceuticals Inc., Boehringer Ingelheim International GmbH, Boehringer Ingelheim Corporation, and Boehringer Ingelheim Pharma GmbH & Co. Kg (collectively, "Plaintiffs") filed this patent infringement suit against Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") on July 23, 2023 (Plaintiffs and Apotex collectively, the "Parties");

WHEREAS, U.S. Patent No. 9,486,526 (the "'526 patent") is assigned to Plaintiff Boehringer Ingelheim International GmbH;

WHEREAS, U.S. Patent No. 10,034,877 (the "'877 patent") is assigned to Plaintiff Boehringer Ingelheim International GmbH;

WHEREAS, Plaintiff Boehringer Ingelheim Pharmaceuticals Inc. is the holder of NDA No. 201280 for linagliptin, for oral use, in 5 mg dosage, which is sold under the trade name TRADJENTA®;

WHEREAS, the '526 and '877 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") with respect to TRADJENTA®;

WHEREAS, Plaintiffs received a letter from Apotex on or about May 8, 2023 stating that Apotex had submitted ANDA No. 218552 to market a generic version of TRADJENTA® (as amended, supplemented, or replaced, "Apotex's ANDA Product");

WHEREAS, Plaintiffs allege, and Apotex denies, that Apotex's ANDA Product infringes the '526 and '877 patents, and Apotex alleges, and Plaintiffs deny, that the '526 and '877 patents are invalid;

WHEREAS, Plaintiffs and Apotex are currently engaged in discovery and a bench trial in this action is scheduled on November 17, 2025;

WHEREAS, Plaintiffs have filed patent infringement suits against Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan Laboratories, Limited, including Case

Nos. 1:20-cv-19 and 1:20-cv-90 in the Northern District of West Virginia (the "Mylan Case");

WHEREAS, Plaintiffs have alleged infringement of the '526 patent in the Mylan Case;

WHEREAS, the outcome of trial in the Mylan Case may provide additional clarity regarding the claims and defenses in this case;

WHEREAS, Plaintiffs and Apotex want to avoid unnecessary cost and expenses in litigating this case.

NOW, THEREFORE, IT IS HEREBY STIPULATED by Plaintiffs and Apotex, subject to the approval of the Court, that:

1. This case shall be immediately stayed, and all currently scheduled pretrial and trial dates vacated.

2. The stay shall remain in place until the earlier of the following: (i) the date on which any entity other than Plaintiffs and Apotex offers for sale or sells in the United States a linagliptin-only pharmaceutical product that has received FDA approval for marketing in the United States (including an authorized generic version of a linagliptin-only pharmaceutical product under NDA No. 201280 without the TRADJENTA® trade name or any replacement trade name, but excluding product sold by Plaintiffs with the TRADJENTA® trade name or any replacement trade name); (ii) the date of a district court decision on the merits in the Mylan Case, (iii)

the date of dismissal of the Mylan case before a district court decision on the merits; (iv) the date the '526 patent is no longer asserted in the Mylan Case, (v) the date the Mylan Case is stayed; or (vi) following October 5, 2025, thirty (30) days after either Party provides written notice of electing to proceed with this litigation (a "Stay Ending Event"). Upon a Stay Ending Event, the Parties shall jointly petition the Court to vacate the stay.

3. Plaintiffs and Apotex agree that the resolution (excluding any award of fees, costs, or other enhanced damages) of Mylan's challenges to the validity of the '526 patent in the Mylan Case (including appeal, if applicable) shall be binding in this litigation as to the validity of the '526 patent and '877 patent (*e.g.*, if the '526 patent is found to be valid in the Mylan Case, the Parties agree that the '526 patent and '877 patent are valid for purposes of this litigation, and if the '526 patent is found to be invalid in the Mylan Case, the Parties agree that the '526 patent and '877 patent are invalid for purposes of this litigation).

4. Plaintiffs and Apotex agree that if Mylan's linagliptin-only pharmaceutical product (including the product described in ANDA No. 208431, as amended, supplemented, or replaced) ("Mylan's ANDA Product") is found not to infringe the '526 patent in the Mylan Case (including appeal, if applicable), Apotex's ANDA Product will likewise be deemed not to infringe the '526 patent and '877 patent. For clarity, a finding that Mylan's ANDA Product infringes the '526 patent

in the Mylan Case (including appeal, if applicable) shall not be binding (and all of Apotex's non-infringement defenses shall be preserved) with respect to Apotex's ANDA Product.

[redacted]

6. Plaintiffs and Apotex acknowledge and agree that this stipulation does not provide Apotex with a license to any patents owned or controlled by Plaintiffs nor does this stipulation constitute a covenant not to sue with regard to Apotex's ANDA Product or any patents owned or controlled by Plaintiffs.

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April 4, 2025

SO ORDERED, this _____ day of _____, 2025.

The Honorable Colm F. Connolly
Chief, United States District Court Judge